FIU Engineering & Computing

Department of Biomedical Engineering

hosts

9th Annual International Conference on Ethics in Biology, Engineering, & Medicine

April 14th & 15th, 2018

Welcome from the Conference Chairs

We are pleased to welcome you to the Ninth International Conference on Ethics in Biology, Engineering, and Medicine, hosted by the Department of Biomedical Engineering at Florida International University. Our mission is to bring together biomedical engineers, scientists, clinicians, philosophers, lawyers, and entrepreneurs to engage in a dialogue about the ethical challenges that face us during this rapid period of technological advancement and scientific discovery. Our lives and societies are shaped by scientific progress more now than at any time in history, which places a heightened imperative on our collective treatment of the ethical challenges that arise from this process. The work presented here will cover a broad range of topics reflecting the exciting and controversial nature of new advances in biology, engineering, and medicine.

This conference is sponsored by Florida International University's Biomedical Engineering department. It is co-sponsored by the American Institute for Medical and Biological Engineering, the American Society for Bioethics and Humanities, Sigma Xi - The Scientific Research Society, the Society on Social Implications of Technology, the Biomedical Engineering Society, International Federation of Medical and Biological Engineering, and more.

Many people contributed to the success of this conference. We would like to thank the Keynote speakers, invited speakers, authors, poster presenters, session moderators, panel members, and staff. We hope you find this conference to be an intellectually rich and stimulating experience.

Welcome to Miami, Florida,

Zachary Danziger and Subrata Saha

Conference Chairs of ICEBEM9, 2018

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KEYNOTE SPEAKERS

Jonathan Moreno, Ph.D.
University of Pennsylvania

Professor of Ethics in the University of Pennsylvania's Department of Medical Ethics and Health Policy. He has served on numerous panels in bioethics, including "Progress in Bioethics" at the Center For American Progress in Washington D.C. and is the author many books engaging with ethics of science, including "The Body Politic: The Battle Over Science in America".

Kenneth Goodman, Ph.D., FACMI
University of Miami

Professor of Medicine at the University of Miami in the Departments of Philosophy, Health Informatics, Public Health Sciences, Electrical and Computer Engineering, Nursing and Health Studies, and Anesthesiology. He directs the Florida Bioethics Network and chairs the UHealth/University of Miami Hospital Ethics Committee. His long track-record of ethics research focuses on technology in public health, and is the author of the recent book "Ethics, Medicine, and Information Technology: Intelligent Machines and the Transformation of Health Care."

INVITED SPEAKERS

Sheldon Krimsky, Ph.D.
Tufts University

Professor of Urban and Environmental Policy and Planning at Tufts University. He is the author or editor of over 20 books relating to science and ethics, including "Stem Cell Dialogues: A Philosophical and Scientific Inquiry Into Medical Frontiers" and "Race and the Genetic Revolution: Science, Myth, and Culture".

Wade L. Robison, Ph.D.
Rochester Institute of Technology

Professor of Applied Ethics at the Rochester Institute of Technology in the Department of Philosophy. He is the recipient of numerous National Endowment for the Humanities fellowships, was the President of the International Hume Society and is the author of the acclaimed book "Decisions in Doubt: The Environment and Public Policy." His featured lecture at ICEBEM9 will cover the topic of how we bring our own value-propositions to even the most seemingly objective scientific issues, such as a simple graph of quantitative data, and how we can begin to understand this process and its implications.

Monique Frize, Ph.D.
Carleton University and Canada University Ottawa

Professor of Systems and Computer Engineering at Carleton University and Canada University Ottawa. She has worked as a clinical engineer and was the first appointed holder of the Nortel-NSERC Women in Engineering Chair at the University of New Brunswick. Her research interests include medical decision support systems and medical technology management. Her talk will cover the ethics of the implementation of regulatory frameworks that lag behind the rapid development of technologies that have broad societal impacts.

Agenda

Saturday, April 14th, 2018

8:00am Breakfast and Registration

8:30am **Welcome and Intro**
John L. Volakis
Dean, College of Engineering and Computing, Florida International University

8:45am **Keynote Speaker**
Jonathan Moreno, Ph.D.
University of Pennsylvania

9:45am Announcements

10:00am Coffee Break

SOCIAL IMPLICATIONS OF BIOTECHNOLOGY
Session Chairs: Dr. Ranu Jung & Dr. Shankar Krishnan

10:30am **X 5: Challenges of Health Equity in Genomic Medicine and Research**
Canon Brodar
University of Miami Miller School of Medicine

10:45am **X 6: Crossing Political Morality & Public Health Ethics. The Case of Healthcare Cost & Quality in India**
Dr. Amit Chattopadhyay
Hindu University of America, Department of Oral and Maxillofacial Medicine and Diagnostic Sciences, CWRU School of Dental Medicine

11:00am **X 23: Affordable Access to Cancer and Other Lifesaving Drugs in the United States**
Dr. Evaristus Chiedu Obi
Duquesne University, Center for Healthcare Ethics

11:30am **X 17: Ethics in gender wage gaps in healthcare and medicine**
Dr. Uma G. Gupta
State University of New York at Buffalo State

11:45am **X 33: Face Transplants: Ethical and Social Issues: An Anticipatory Ethical Analysis**
Dr. Richard L. Wilson 1; Dr. Michael W. Nestor 2
Department of Philosophy, Loyola University 1; Computer Science and Information Systems, Towson University 2

12:00pm **X 29: Human death and a human determination of the moment of death - a study of the stormy debate over brain death and organ donation in Jewish law**
Dr. Irit Offer Stark
NYU school of Law

12:15pm Lunch

Agenda

Saturday, April 14th, 2018

GLOBAL BIOETHICS
Session Chairs: Dr. Luis Kun & TBA

1:15pm **X 8: Developing a Common Concept of Global Ethics - Needs, Problems and Potential Solutions**
Dr. Amit Chattopadhyay
Hindu University of America, Department of Oral and Maxillofacial Medicine and Diagnostic Sciences; CWRU School of Dental Medicine

1:30pm **X 24: The Establishment of Comprehensive Primary Health Care as a Critical Function of South-South Cooperation to Help Member Countries Combat Health Disasters**
Dr. Evaristus Chiedu Obi; Dr. Peter I. Osuji
Duquesne University, Center for Healthcare Ethics

1:45pm **X 28: Ethical Challenges for Human Subjects Research in Collaboration with Foreign Countries**
Meghamala Sinha 1; Dr. Subrata Saha 2
Oregon State University 1; Florida International University, Department of Biomedical Engineering 2

2:00pm **X 31: Bioterrorism, Biocrime and Biohacking: Anticipating the Ethical Issues**
Dr. Richard L. Wilson 1; Dr. Michael W. Nestor 2; *Department of Philosophy, Loyola University 1; Computer Science and Information Systems, Towson University 2*

2:15pm **X 1: Need for Culturally Sensitive Bioethical Guidelines**
Dr. Ram P Agarwal
University of Miami, Miller School of Medicine

2:30pm **X 32: Zika Eradication A Multidisciplinary and Anticipatory Ethical Analysis**
Dr. Richard L. Wilson 1; Dr. Michael W. Nestor 2; *Department of Philosophy, Loyola University 1; Computer Science and Information Systems, Towson University 2*

2:45pm **X 9: Neuroethics: "Consciousness" Ecological Attributes and Linking it to Human Attributes A Vedantic Approach**
Dr. Amit Chattopadhyay
Hindu University of America, Department of Oral and Maxillofacial Medicine and Diagnostic Sciences; CWRU School of Dental Medicine

3:00pm Coffee Break

Agenda

Saturday, April 14th, 2018 (cont.)

3:30pm — ***Pannel Discussion***
X 10: Ethical Prevention and Management of a Hydrogen Fluoride Disaster
Dr. Sharon Petronella Croisant 1; Mike Mastrangelo 2; Dr. Evelyn "Bernadette" McKinney 3
Institute for Translational Sciences, University of Texas Medical Branch 1,3; Program Institutional Preparedness, University of Texas Medical Branch 2

ETHICS OF NEW TECHNOLOGIES
Session Chairs: Dr. Zachary Danziger & Dr. Jamie L. Vernon

4:30pm — **X 13: Examples of Contemporary Technologies Raising Ethical Concerns**
Invited Speaker Dr. Monique Frize
Systems & Computer Engineering, Carleton University, Ottawa, Canada

5:00pm — **X 34: Healthcare and Wearable Technology: Anticipatory Medical Ethics**
Dr. Richard L. Wilson 1; Dr. Michael W. Nestor 2
Department of Philosophy, Loyola University 1; Computer Science and Information Systems, Towson University 2

5:15 — **X 35: Tele Surgery and Virtual Reality: Robotic Assisted Surgery Anticipating the Ethical Issues**
Dr. Richard L. Wilson 1; Dr. Michael W. Nestor 2
Department of Philosophy, Loyola University 1; Computer Science and Information Systems, Towson University 2

5:30pm — **X 26: Ethical Engineering of Synthetic Biology Utilization & Effects**
Darrell Robinson
Binghamton University SUNY

5:45pm — **X. 37: The Bioethics of Implantable Biohybrid Systems**
Dr. Ranu Jung; Andres Pena
Florida International University Department of Biomedical Engineering

6:00pm — Reception/Break

6:30pm — Dinner

Agenda

Sunday, April 15th, 2018

8:00am — Breakfast and Registration

8:30am — Announcements/Welcome

BIOENGINEERING ETHICS EDUCATION
Session Chairs: Dr. Katina Michael & Dr. Subrata Saha

8:45am — **X 2: Navigating ethics in a STEM training grant**
Monica Delgado 1; Allyson Hughes 2; Carlos Serna III 3; Sandra Oviedo Ramirez 4; Osvaldo F. Morera 5; Dr. Guadalupe Corral 6; Dr. Thomas Boland 7
Biomedical Engineering, University of Texas at El Paso 1,3,7; Department of Psychology, University of Texas at El Paso 2,5; Research and Evaluation and Assessment Services, The University of Texas at El Paso 4,6

9:00am — **X 12: Computer Programming Literacy for Medical Professionals**
Teshaun J Francis
Florida International University, Department of Biomedical Engineering

9:15am — **X 30: Teaching ethics in an Advanced Education in General Residency Program (AEGD): preparing competent general dentists**
Dr. Ram M. Vaderhobli 1; Dr. Linda Centore 2
NYU Langone AEGD residency program/ UCSF School of Dentistry 1; Behavioral Sciences and Community Dental Education, UCSF School of Dentistry 2

9:30am — **X 21: Research Ethics Training for Rising Researchers**
Ashley Miller-Dykeman 1; Eman Ghanem 2
Duke Initiative for Science and Society, Duke University 1; Sigma Xi Scientific Research Honor Society, Research Triangle Park 2

9:45am — **X 15: The Necessity of Training and Collaboration in Animal Studies**
Arezoo Geramipour; Ricardo Siu; Zachary Danziger
Florida International University, Department of Biomedical Engineering

10:00am — Coffee Break

Agenda

Sunday, April 15th, 2018 (cont.)

10:30am **Keynote Speaker**
Kenneth Goodman, PhD FACMI
Professor and Director, Institute for Bioethics and Health Policy University of Miami, Miller School of Medicine University of Miami

11:30am Lunch

RESEARCH INTEGRITY
Session Chair: Dr. Osama Mohammed & William Smith, JD

12:30pm **X 27: Understanding cases within professions**
Invited Speaker Dr. Wade Robison
Rochester Institute of Technology

1:00pm **X 14: Research Misconduct in FDA Regulated Clinical Trials: What Not To Do**
Craig A. Garmendia 1; Dr. Purnima Madhivanan 2
U.S. Food and Drug Administration, Office of Regulatory Affairs, Office of Bioresearch Monitoring 1,2; Florida International University, Robert Stempel College of Public Health & Social Work, Department of Epidemiology 2

1:15pm **X 22: Data problems: A cautionary tale about curve fitting in STEM**
Monica Delgado; Allyson Hughes; Carlos Serna III; Dr. Edward Castañeda; Dr. Thomas Boland; Dr. Osvaldo F. Morera
Biomedical Engineering, University of Texas at El Paso 1,3,5; Department of Psychology, University of Texas at El Paso 2,4,6

1:30pm **X 19: The Monsanto Roundup Litigation: What the Discovery Documents Reveal about Corporate & Journal Ethics**
Invited Speaker Dr. Sheldon Krimsky
Tufts University

1:45pm **X 36: Ethical Guidelines for Authorship**
Dr. Pamela Saha 1; Dr. Subrata Saha 2
Department of Psychiatry University of Washington 1; Florida International University Department of Biomedical Engineering 2

2:00pm Coffee Break

Agenda

Sunday, April 15th, 2018

2:30pm Panel Discussion
Dueling with Dual Use: Ethical and Regulatory Issues in Bioweapon Development
James Giordano

MEDICAL PRACTICE AND ETHICS
Session Chairs: Dr. Charles Rosen & TBA

3:30pm **X 20: The Physician Payment Sunshine Act of 2010: What has it achieved?**
Invited Speaker Dr. Sheldon Krimsky
Tufts University

4:00pm **X 4: "Stem Cell" Therapy for Knee Arthritis Marketing, Science, and Ethics**
Dr. Larry S. Bowman; Dr. Steven L. Martin; Dr. Christopher B. Clemow
Blue Ridge Orthopaedics

4:15pm **X 18: Variability in clinical decisions in implant dentistry: An ethical perspective**
Dr. Ajay Kashi; Dr. Subrata Saha
Florida International University, Department of Biomedical Engineering

4:30pm **X 11: Radiation Ethics in the Era of Digital Health Records**
Dr. David Dinhofer
New York City College of Technology, Brooklyn

5:00pm **X 3: Marketing, Ethics, and Government Regulation of Medical Technologies**
Dr. Larry S. Bowman
Blue Ridge Orthopaedics

5:15pm **X 29: Taking care of our caregivers: ethics of mental health in medical students and doctors**
Polly Rinehart 1; Dr. Pamela Saha 2
University of Queensland Medical School, Brisbane, Australia 1; Psychiatry University of Washington 2

*There will be a Poster Session that will remain open throughout the conference. The names of the poster session papers will be announced at the meeting. Anyone interested in presenting a poster can submit an abstract to the website ICEBEM@fiu.edu or to the conference chairs.

1. Need for Culturally Sensitive Bioethical Guidelines

Dr. Ram P Agarwal

Abstract: Unethical research experiments on human subjects in Nazi camps in Germany, and the Tuskegee Syphilis studies in USA and undesirable consequences arising from rapidly growing knowledge base in natural sciences and developments in technology since the mid twentieth century have raised grave concerns about their judicial use. As a result, bioethics emerged as a new discipline offering four guidelines – autonomy, beneficence, non-maleficence, and justice, for medical practice and biomedical research. Since these developments occurred in the West and Western theologians were involved in framing the guideline the interpretation of the guidelines assumed a strong Western hue, almost ignoring the views of the Eastern cultures. Since religious beliefs and cultural values play an important role in health care practices these guidelines face a strong challenge ensuing debate on their global applicability. For example, whereas, the principle of autonomy places too much emphasis on an individual according to Western practice, Eastern values place equal or more value on family and community that, sometimes, take priority over the individual interest and privileges. Similarly, interpretations of other guidelines also differ between the East and the West. In this presentation we will examine some of these differences from the Hindu point of view as an example of the Eastern bioethical values. The world is now becoming a global village with pluralistic society. Therefore, to provide health care or conduct research in pluralistic society, healthcare providers and researchers must be aware of the ethno-cultural values of other cultures and come to consensus for the culturally- sensitive bioethical guidelines that are applicable globally.

2. Navigating ethics in a STEM training grant

Monica Delgado; Allyson Hughes; Carlos Serna III; Sandra Oviedo Ramirez; Osvaldo F. Morera; Dr. Guadalupe Corral; Dr. Thomas Boland

Abstract: The BUILDing SCHOLARs program is a NIGMS grant to fund STEM researchers in the Southwest. BUILDing SCHOLARs fellows are matched with a local mentor, work on their own research project, and spend summers at research intensive institutions where they are paired with a mentor to gain additional research experience. Because of the nature of the fellows' sudden introduction into the realm of research, instilling and discussing ethics within the STEM field is critical in the early stages of the program and is re-emphasized in the latter parts of the program. Prior to spending summers at partner institutions, fellows are required to complete the Collaborative Institutional Training Initiative (CITI) module in Responsible Conduct of Research (RCR) and enroll in a research intensive course sequence that promotes research foundations (RFC) and research techniques (RDC); which is also open to all students. During this course sequence, the enrolled students learn the best practices for ethical conduct of responsible research, developing a research design, and data interpretation. Introducing the students to the culture of science where the students take ownership of the responsibilities involved in their research project provides for an experience of ethical applications involved in STEM training. Students who completed one RFC took a course evaluation survey at the beginning and the end of the course to gauge the impact of the course on the students' confidence and level of knowledge in research. The differences in scores between the pre- and post-surveys were evaluated with a paired sample t-test. Two items on ethics were analyzed across multiple courses. Students were found to have statistically significant gains in knowledge related to: "Researcher misconduct and questionable practices in research." ($p < .0001$) and "The professional responsibility of scientists (i.e. in relation to intellectual property, competing interests, authorship, etc.)" ($p = .002$). An independent measures t-test results showed differences between the BUILDing SCHOLARS fellows and the other students enrolled in the course, ($p < .0001$). The NIH-supported fellows, on average, received higher scores on the pre-survey on both items than the other students, which may be due to the CITI training that fellows are required to complete. In conclusion, the students who are exposed to ethics during their research experience have a significantly improved sense of professional responsibility.

3. Marketing, Ethics, and Government Regulation of Medical Technologies

Dr. Larry S. Bowman

Abstract: Manufacturers of Medical Devices first came under intense scrutiny in 2005 by the US Department of Justice; the focus was sales and promotional practices. The center of interest was twofold: industry violations of both the Federal Healthcare Anti-kickback Act and the False Claims Act. In 2007 the five firms that produced 90% ($60 Billion) in domestic medical technology products entered a settlement. Four of the five corporations paid fines of $311 million; all five accepted corporate integrity and deferred prosecution agreements. In the ensuing years there have been multiple investigations of manufacturers, representatives and physicians resulting in fines and prison terms for kickback related offenses.

AdvAmed (Advanced Medical Technology Association), a voluntary organization of Medical Device companies adopted a Code of Ethics January 1, 2004; it was revised January 1, 2009. The code was intended to facilitate ethical behavior in the industry; however, there are no enforcement capabilities. The code includes (a) Companies and Health Care Professionals have collaborative relationships that meet high ethical standards, (b) medical decisions are based on the best interest of patients, and (c) Companies and Healthcare Professional comply with applicable laws, regulations, and government guidance. These revisions follow the PhRMA (Pharmaceutical Research and Manufactures of America) Code on Interactions with Healthcare professionals. Both codes significantly limit provider interactions. The elements of the revised code include (a) Compliance, (b) Company conducted product training and education, (c) Support of third party educational conferences, (d) Sales, promotional, and other business meetings, (e) Consulting arrangements with Healthcare Professionals including royalties, and (f) Prohibition on entertainment, and recreation. This increasing focus by companies on compliance will produce greater attention on Healthcare Providers.

In 2007 94% of physicians had a relationship with industry, 83% received gifts and 28% received payments for services such as consulting and research participation. Recoveries from industry and Healthcare Providers are currently in the billions. The Physicians Payment Sunshine Act (Section 6002 of the Affordable Healthcare Act) requires medical product manufactures to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals with data collection beginning in 2013.

There have been numerous medical technology advances; however, the physician – patient relationship is still the center of focus for all ethical concerns. Industry and professional organizations devote increasing emphasis on ethics for a reason. "DO NO HARM" includes ethical quality of care and cost containment, without inhibiting research.

4. "Stem Cell" Therapy for Knee Arthritis Marketing, Science, and Ethics

Dr. Larry S. Bowman; Dr. Steven L. Martin; Dr. Christopher B. Clemow

Abstract: There is considerable consumer excitement for Orthobiologics ("stem cell") therapy for knee arthritis. Although in-vitro studies have provided some promise in multiple Ortobiologic fields; there is a significant paucity of well designed in-vivo research documenting their effectiveness. The cost of $1800- $6000 for each treatment with no significant double blind prospective studies creates an ethical dilemma for the practicing healthcare provider. These procedures are not covered by insurance. The only current published study of 25 bilateral arthritic knees demonstrated improvement following the use of "stem cells"; however, there was improvement in both arthritic knees with one being injected with placebo. Several different options for Orthobiologics ("stem cell") therapy include freeze dried and reconstituted amnionic stem cells, bone marrow aspirate, adipose tissue treated cells, Platelet Rich Plasma (PRP), and Growth Factor. More than 1,000 centers for these treatments have been established throughout the country. Patients with knee arthritis pay thousands of dollars out of pocket with the hope of avoiding knee replacement. Practitioners with no formal training in orthopedic care diagnose and treat these conditions representing themselves as experts. Procedures include infra-articular injections of these materials without adequate evaluation and discussion of other treatment modalities.

FDA regulation of human cells, tissues; as well as, cellular and tissue based products (HCT/P's) are primarily regulated by Section 361 of the Public Health Service Act (PHSA). These products must meet certain requirements to include minimal manipulation during processing, homologous only, must not be a combination product, and has no metabolic or systemic effect. As of February 2017 the FDA has not finalized the HCT/P guidance. There has been little enforcement action related to HCT/P products currently on the market; allowing, companies to self designate compliance with the requirements and bring the products to the market in 1– 2 years. This is in sharp contrast for products that require a Biologic License Application (BlA) under Section 351. Preclinical and a three phase clinical studies must be completed prior to FDA approval. Under this section the approval process takes generally 10 years or longer.

The lack of well controlled clinical trials of "Stem Cells" without documented risks and benefits is worrisome. The Orthobiologics ethics consortium was formed in 2017 by a multidisciplinary group of Healthcare Professionals. Their recommendations include (a) training and application within scope of practice, (b) obtaining informed consent with published outcomes and treatment options, and (c) advertising and marketing claims substantiated by publically available data. The proliferation of these treatments creates a moral and ethical dilemma. Marketing should not progress faster than the science in any medical treatment.

5. Challenges of Health Equity in Genomic Medicine and Research

Canon Brodar

Abstract: Genomic medicine is seen by many as the future of medicine, integrating emerging genetic and genomic information and technology into clinical settings. Precision medicine further promises an approach that incorporates genetic/genomic, environmental, and behavioral factors affecting health. In the United States, the National Institutes of Health's Precision Medicine Initiative (PMI) and its cohort project, the All of Us Research Program, intend to advance these goals by recruiting and studying at least 1 million participants. The program advertises explicit commitments to recruiting a diverse cohort and incorporating patients as partners. Their focus on inclusivity is particularly interesting, as it may demonstrate an equity-based approach to racial and ethnic disparities in genomic science and medicine.

Genetics/genomics research has historically involved mostly white participants with homogenous European ancestry. As further studies are built on this science, any knowledge and potential therapies derived from current research may be structured to preference white patients. Ethical discourse around genomic medicine often centers around autonomy, consent, and privacy, but this is a question of justice. Specifically, this is a problem of racism. The All of Us Program's solution is to make research more inclusive by involving more diverse participants. Recruitment is intended to include communities that have often been systematically excluded or mistreated by medical and scientific institutions, which further raises questions of beneficence.

While this kind of inclusivity in research may be viewed as a matter of equity, we must acknowledge that it still involves a clear power dynamic, where powerful researchers draw on the resources of vulnerable communities. For a notable example, the Human Genome Diversity Project (HGDP) also sought to study a diverse set of populations, only to be accused of vampirism. While the context and content of the All of Us Program is new and different from the HGDP, there will be similar challenges in engaging with participants, and both projects point to an interesting ethical dilemma in genomics: Research either involves passive participation in one form of racism, or active engagement in work that may be exploitative. Clinicians and scientists should respond to these problems by working to incorporate methods and develop projects that more clearly promote health equity.

6. Crossing Political Morality and Public Health Ethics. The Case of Healthcare Cost & Quality in India

Dr. Amit Chattopadhyay

Abstract: Controlling healthcare costs is a major issue that has never been adequately achieved anywhere. Furthermore, providing good quality healthcare on an average has also been problematic in different populations, especially in the developing world. To add to this, development and implementation of an ethical approach aimed at and achieving an overall optimal health status of the population has not been adequately discussed in the developing world. Countries such as India aspiring to become industrialized and improving healthcare services to the population face major ethical headwinds in trying to establish a reliable and responsive healthcare system. Key problematic areas include political will, financial constraints, opportunistic approach, underdeveloped/ undeveloped ethical framework for healthcare education services and policies. Political opportunism and expired and backward-looking political morality prevent development of a fair system of healthcare delivery. Three major areas of focus should be the priority of governments attempting to improve health of their populations: Available healthcare; Affordable healthcare; and Quality healthcare. Problems in all these three areas characterize the Indian healthcare system. The national government and state governments have taken several steps to address these issues such as price caps, forced outreach for interns, establishment of punitive commissions against private hospitals, and ad-hoc responses to public health issues. The Medical Council of India deals with medical negligence cases. However, as any fledgling system, these components of the Indian healthcare system bring several problems with them from ethical stand-point (among other problems). This phenomenology, ethnographic and critical research study will assess the ethical issues of the system in an effort to develop a pathway forwards towards a more humane, equity-based and rational system within the constraints of the socio-economic-political environment.

7. Understanding the Fundamental Tenets of Bioethics – Culture-sensitive Silos of Ethics vs. Multiculturalism/ Pan- humanism/ Universalism

Dr. Amit Chattopadhyay

Abstract: The world is inhabited by societies, which different stages of development, characterized by different cultures, religion, political attributes, and languages. As long as such cultures were contained within themselves and not well connected to the rest of the world, their ethical development also occurred within the confines of their population attributes. In a world that is well-connected and where information technology has brought information (good and bad) to the fingertips of every individual quickly, across barriers such as educational background, social status, economic status or awareness levels, a key question that needs to be asked is: Is a "silo-ed" approach (based on population sub-group characteristics) to development of ethics based on individual culture-sensitive population a rational way to approach the future? Alternately, should one wish for and expect multi-culture inclusive, evidence-based rational and universal ethics that are applicable to all of humanity? Does such an approach have any utility? This ethnographic study will discuss ethical analysis of these two broad categories to propose a pathway for development of ethical approaches and applications for the future.

8. Developing a Common Concept of Global Ethics - Needs, Problems and Potential Solutions

Dr. Amit Chattopadhyay

Abstract: Global ethics as a concept tries to provide a foundation and platform for ethical interaction between a variety of people and their various levels of organization in the society across the world. Currently it is a complex and ill-defined set of ideological and philosophical claims about the de-facto and ideal norms which guide the interactions of people and communities around the world. Global ethics is characterized by: differences and disparities in the world; absence a common concept of global ethics; varied application and interpretation of human rights and freedoms; multiple economical, cultural and political dimensions of global ethics; and multiple relativisms. This critical research study tries to answer the questions: 1. Is global ethic useful (?); 2. Should goals for global ethics be aspirational or actionable(?); and 3. What is the future of Global ethics?

9. Neuroethics: "Consciousness": Ecological Attributes and Linking it to Human Attributes – A Vedantic Approach

Dr. Amit Chattopadhyay

Abstract: Consciousness is an enigmatic property of the universe. Humans have defined and assessed consciousness differently. Three broad themes have been used to define and assess consciousness: 1. A phenomenon characteristic of human beings of unknown origin (attributed to the God of religions), the property of which makes humans aware; 2. A product of brain activity through which humans act and become aware of the worldly phenomenon; and 3. A characteristic of the universe that is the primary cause of the apparent universe to exist (Vedantic approach – "vedantic" – originating from the vedas). Theme # 1 simply assumes consciousness as "given" and does not question its nature of characteristics. Studies have been designed to assess the characteristics of consciousness as in themes # 2 and 3 above. Some experiments have tried to use theme # 3 to impact social events (Sri Aurobindo, an Indian revolutionary turned vedantic sage tried to expiscate an understanding of consciousness using the Greek concept of "overmind" and conducted some experiments using this idea). The vedantic approach views consciousness as a property of the universe at an ecological level and as the ultimate truth to which humans should aspire. However, the pathway to reach such ecological-level consciousness is thought to be through meditation alone. Ongoing scientific research in neurology is exploring the functions of brain in various mental phenomenon and meditation. This descriptive and review critical research hypothesis generating study tries to bring together these concepts of consciousness in vedantic philosophy and neurology to find commonalities and provide possible areas of further research into the "sources" of ethical understanding and behavior of human beings.

10. Ethical Prevention and Management of a Hydrogen Fluoride Disaster

Dr. Sharon Petronella Croisant; Mike Mastrangelo; Dr. Evelyn "Bernadette" McKinney

Abstract: This panel will outline current understanding of the risks, resource needs, disaster plans, and ethics associated with prevention and management of a Hydrogen Fluoride (HF) or hydrofluoric acid disaster. Oil refining is an important economic engine for the U.S. Gulf Coast. HF, a toxic substance that in small amounts can cause severe burns, lung damage, even death, is used in oil refining in large volumes to increase the octane of gasoline. A release of the substance can result in a toxic persistent vapor cloud that can drift for miles under certain atmospheric conditions, potentially causing harm to thousands of people, animals, and plants. Communities near refineries are generally unaware of the dangers. Health-care facilities are poorly equipped to cope with large numbers of those exposed, and first responders along HF transportation corridors are often times inadequately trained to respond to HF incidents. While those exposed to concentrated HF will feel immediate and intense pain, those exposed to low concentrations of hydrofluoric acid (e.g. < 20% concentration) may not be aware of the exposure until several hours have passed. No rapid assessment tool currently exists to identify these silent exposures. The best available treatments are calcium gluconate and symptom control, however; calcium gluconate has been on the national shortage list since 2013. Human trials to test treatments would be unethical. Given the natural and man-made threats to Gulf Coast oil refineries (e.g., hurricanes and terrorism), and the consequent possibility of cascading failures that result from hurricane floods, planning to address a hydrofluoric acid disaster is vital.

11. Radiation Ethics in the Era of Digital Health Records

Dr. David Dinhofer

Abstract: The use of ionizing radiation in health care continues to be a mainstay for diagnosis and treatment. Over the past 100 years since the discovery of x-rays, the benefits of the use of ionizing radiation is so strong that the consideration of the risk benefit ratio is an afterthought which would not be acceptable had it been discovered today. The current risk model is based on research from the Hiroshima and Nagasaki nuclear bomb explosions. Although this model has been updated many times, it still relies on data that is over 70 years old and fails to evaluate effects of low dose radiation exposure. With the advent of digital records, the ability to query huge data archives, and statistical software tools, we have the ability to more accurately examine the effects of low dose ionizing radiation exposure. This information could be used to develop risk models at specific dose levels. Digital records also offer the ability to evaluate risk benefit models of the outcomes based on the information obtained from the diagnostic exam or treatment protocol. This would allow the healthcare community to present more accurate information about the risk/benefit model to be used in shared decision making. Additionally, computer presentation models are more easily created that can be used to demonstrate the models to patients to help them understand this information

and make better more informed decisions about their healthcare as part of a shared decision making process.
In the future, data repositories can be created to store individual radiation dose information so that individuals can have personal access to radiation exposure and its risk. This would fulfill the mandate of patient centered care which is part of the ACA focus. This will also lead to improvements in our understanding of radiation injury and its role in healthcare.
It is the author's hope that this paper will be used to promote research in these areas and reduce roadblocks to acceptance and access to health information data. Also, the author hopes that this paper will create an incentive to provide access to information by patients and providers with a goal of continuous improvement in the accuracy and understanding of the effects of low dose radiation.

12. Computer Programming Literacy for Medical Professionals

Teshaun J Francis

Abstract: With the current rate of advancement in biotechnologies, we will need to ensure that our future physicians have the technical knowledge they need to stay active in the field. Today, the biomedical revolution is led by computational medicine, in the form of machine learning and data mining, which is an attempt to augment a physician's diagnostic ability with that of a machine. Unlike traditional medical tools, these softwares are data-driven algorithms designed to identify patterns in biosignals and 'diagnose' patients by fitting them to a known disease. In order for these technologies to be properly integrated however, physician participation is imperative during development, application, and post-hoc evaluation stages. This will require that medical doctors have a fundamental 'programming literacy' for them to stay active in the future of medicine. Medical school programs will need to introduce courses that teach computer science principles so that they can foster a new generation of programming proficient medical professionals. If we fail to implement 'programming literacy' in the medical field, we risk cases of stolen patient data by cyber security breaches, misdiagnoses from improper interpretations of computational analyses, and stagnation of medical research without physicians to collaborate.

13. Examples of Contemporary Technologies Raising Ethical Concerns

Invited Speaker Dr. Monique Frize

Abstract: Although all technologies have an impact on society and people, several recent technological developments raise new ethical questions that must be examined, understood, and dealt with. It is a known fact that technology development precedes regulation and the creation of laws to control negative consequences. Thus it is critical that ethical examination of these new developments be studied simultaneously. The presentation will provide a few examples of ethical concerns that include: Stem cells, nanotechnologies, physician-assisted suicide, and autonomous vehicles.

14. Research Misconduct in FDA Regulated Clinical Trials: What Not To Do

Craig A. Garmendia; Dr. Purnima Madhivanan

Abstract: To bring new medical advancements for biological products, medical devices, and/or pharmaceuticals to the public, clinical trials must be performed and submitted to regulatory agencies, which in turn may audit these clinical trials. These audits have identified clinical research misconduct, which can fall into one or more of five categories: (1) the fabrication of data or results and its recording and reporting; (2) the manipulation of data so that it no longer accurately reflects what was observed; (3) plagiarism; (4) the repeated and systematic deviation from the established protocol; and/or (5) the violation of human subject rights and protections. U.S. Food and Drug Administration (FDA) regulated clinical trials are the most stringent clinical trials performed in the world, but even these clinical trials are not impervious to research misconduct. The analysis of regulatory violations observed and cited by the FDA can provide insight into research misconduct that can, and has, occurred. In addition, an overview of high profile cases, such as the University of Pennsylvania gene therapy trial, University College London implantations, and the Bial-Portela clinical trial, highlight the grave consequences research misconduct can have on human subjects and the clinical research personnel.

15. The Necessity of Training and Collaboration in Animal Studies

Arezoo Geramipour; Ricardo Siu; Zachary Danziger

Abstract: Animals have been used for biomedical, behavioral, agricultural, and pharmaceutical research as far back as Ancient Greece. Animal research stems from the concept that certain animal models are anatomically and physiologically similar to humans and can thus be used as a proxy for development of human treatments, technologies, and surgical approaches.
Biomedical engineering research is heavily dependent on animal studies to develop new technologies. Among the key areas of research, the acquisition of physiological parameters and signals can be considered one of the most important steps. However, biomedical engineers might lack the skill sets required to properly obtain these data as a broad knowledge of surgical techniques, anatomy, physiology, and animal behavior might be required. Typically, biomedical researchers start the data acquisition process after theoretical knowledge and gain the practical knowledge through the use of practice animals. These practice animals are used for training and if the learning curve is slow, due to lack of skill or difficulty of the procedure, a large number of practice animals might end up being used. Furthermore, faulty experimental data can lead to misinterpretation of results that can lead to not only unnecessary expenditure of time and resources but to more impactful consequences such as potentially deadly treatments or misinformed health policy.
To reduce the number of animals used, refine surgical and experimental procedures, and promote proper collection of biomedical data, we suggest promoting collaborations between different fields to compensate for the weaknesses of biomedical researchers, in particular medical practitioners. Medical practitioners, through extensive training, have a knowledgebase that can be utilized to maintain animal subjects in the most optimal physiological state and are practiced in surgical procedures to expose locations where treatment can be applied or data collected. However, due to the inherent demands of the medical practice, medical professionals rarely have the opportunity and availability to assist in research. However, medical students still in training might both be able to assist researchers and obtain practical training.
In this paper we aim to discuss the problems associated with the lack of medical expertise in biomedical researchers and the advantages and disadvantages of using medically trained personnel for training and assistance in biomedical engineering research.

16. Ethics and Computational Bioscience

Dr. Kenneth W. Goodman

Abstract: The nature and goals of biomedical research have shifted in a breathtakingly short time. The transition from hypothesis-driven science to knowledge discovery in data bases has replaced centuries of scientific standards with tools that analyze not the world but data and information apparently about the world. The software for accomplishing this adheres

to few if any standards, is not clearly fit for the purposes to which it is put and, sometimes, is guided more by intellectual priority and property than the desire to conduct more reliable and reproducible scientific inquiry. Moreover, when such systems are used for decision support, the challenges related to accountability, responsibility, peer review and appropriate uses and users emerge as fundamental to the scientific enterprise.

17. Ethics in gender wage gaps in healthcare and medicine

Dr. Uma G. Gupta

Abstract: The Equal Pay Act of 1963 was an important step forward in achieving the national goal of equal pay for equal work. While the pay gap has narrowed in some sectors, it continues to be a persistent and evasive problem in many industries, including medicine and heath care. These gaps extend beyond pay. They include opportunities for promotion, leadership positions, government and industry funded research, battling outdated workplace policies that work against women, and social representation of the medical profession. Pay-for-performance programs, among many such pathways and programs, were designed to address the pay gaps by using meritocracy as a guiding principle. Given that women make up nearly 50% of students entering medical school and PhD programs, the persistent gaps of disadvantage that women face raises ethical issues.

Many studies, research reports, and white papers have examined this issue, within theoretical, empirical, and anecdotal frameworks and not surprisingly, the solutions and call to action to advance women in medicine and healthcare have a uniform theme to them, regardless of the source of the investigation or research study. Early evidence points to abundant of innovative ideas and solutions at the organizational, positional, and individual level to address the wage gap and other discriminatory practices. However, what seems to be lacking is the will to execute and an interplay of ethical issues by leaders who understand the law, but are driven by commercial goals to skirt the spirit of the law.

This paper provides a framework for discussing the ethical issues and challenges that confront decision-makers and employees in healthcare.

18. Variability in clinical decisions in implant dentistry: An ethical perspective

Dr. Ajay Kashi; Dr. Subrata Saha

Abstract: The use of implants to treat patients with tooth/teeth loss is growing rapidly. With the advent of newer implants and treatment options available including the plethora of choices patients can be overwhelmed in making informed decisions. Further in the current academic curriculum there are no universally accepted guidelines available for clinicians to be trained to the same proficiency in implant dentistry. Consequently treatment options that become available to patients can vary depending on the training that the clinician has. For instance a novice clinician might be proficient in using a single implant system thereby limiting his treatment options. Alternatively an experienced clinician might be able to provide patients with multiple treatment options. This poses an ethical dilemma for the treating dentist, particularly when he/she favors an implant system which may not be the industry standard. The question of patients facing multiple treatment options that might conflict with the accepted standard of care is also a matter of concern. Solutions to address forthcoming problems faced by clinicians as well as patients need to be discussed in academic/implant training programs.

19. The Monsanto Roundup Litigation: What the Discovery Documents Reveal about Corporate & Journal Ethics

Invited Speaker Dr. Sheldon Krimsky

Abstract: In 2015 the International Agency for the Research on Cancer (IARC), an independent research group under the auspices of the World Health Organization, reached a determination that the chemical glyphosate, the active ingredient in many formulations of a popular herbicide, is a probable human carcinogen. Subsequent to the finding, several hundred legal cases were filed against Monsanto Corporation, the manufacturer of the herbicide Roundup, one of the most widely used glyphosate-based products. As of November 2017, roughly 3,500 plaintiffs were suing Monsanto alleging they or their loved ones developed non-Hodgkin lymphoma due to Roundup exposure, and that Monsanto had long covered up the risks of the glyphosate-based herbicide. More than 270 of the cases have been consolidated in multi-district litigation (MDL) for oversight by one judge in the U.S. District Court in San Francisco. Many other lawsuits are proceeding in state courts. As part of the litigation, Monsanto has turned over millions of pages of internal records to plaintiffs' attorneys and many of those documents have been made public through the court docket. Both these disclosed discovery documents and hundreds of other court documents have been placed in the public domain.

I shall discuss the discovery documents as well as freedom of information documents obtained from regulatory agencies and public universities for evidence of corporate malfeasance and undisclosed conflicts of interest with respect to issues of scientific integrity.

20. The Physician Payment Sunshine Act of 2010: What has it achieved?

Invited Speaker Dr. Sheldon Krimsky

Abstract: In 2010 Congress enacted the Affordable Care Act. Sec 6002 was subtitled the National Physician Payment Disclosure Program, aka Physician Payment Sunshine Act (PPSA). It requires manufacturers of drugs, devices, biological medical supplies to report certain payments or transfer of value to physicians, other health care workers and teaching hospitals. Among the goals of PPSA is to discourage inappropriate payment to physicians; to encourage choice of physicians and medical decisions with the knowledge about industry payments in mind; to mitigate the total amount of influence that the pharmaceutical and device industries exercise over medical research.

The talk will address: whether there is any evidence that the PPSA has changed institutional behavior regarding the acceptance of gifts to physicians, medical students including corporate-funded lunches; whether the patients' right of access to information about corporate payments to physicians results in the actual access or use of such information; whether the mere knowledge that such information exists elevates the patients' trust in their physicians or in the medical community.

21. Research Ethics Training for Rising Researchers

Ashley Miller-Dykeman ; Eman Ghanem

Abstract: Early research experiences have become increasingly available to high school and undergraduate students in Science, Technology, Engineering, and Mathematics (STEM) fields. However, these opportunities are rarely coupled with a formalized and engaging training that educates students about ethics in scientific research. This may result in students unknowingly falling victims of research misconduct, which has serious consequences and is detrimental to the research community. Presented here, is a pilot for an initiative that aims at developing standardized training modules for introducing rising researchers to responsible conduct of research. We have developed six modules that are based on group activities and case studies. The modules cover crucial research ethics topics such as professionalism in research, data management, handling conflicts of interest, bioethics, and understanding and managing pressures in scientific

research. Each module consists of a short presentation or discussion followed by an activity developed to facilitate student participation. Federal as well as published recommendations were considered in selecting the content of these modules. The modules are designed for high school students and can be easily adapted to target more advanced students across disciplines. Sigma Xi is committed to research integrity and to cultivating the next generation of researchers. This initiative is another step on the path to strengthening the research enterprise by educating rising researchers about the importance of ethics in research.

22. Data problems: A cautionary tale about curve fitting in STEM

Monica Delgado; Allyson Hughes; Carlos Serna III; Dr. Edward Castañeda; Dr. Thomas Boland; Dr. Osvaldo F. Morera

Abstract: Issues with reproducibility of datasets and misguided data analyses are prevalent in the STEM fields. Specifically, the ethical considerations surrounding implications and certainty of data findings are not always transparent. The points mentioned below should be considered prior to the start of any study and will inform the design of the study. The points that we want to talk about are: (1) model misspecification, (2) detection of outliers, (3) power analysis to determine needed sample size to detect statistically significant correlations, (4) modeling of interactions to detect group differences and (5) emphasizing the need for replication to demonstrate that effects are found across multiple studies. Often researchers assume a linear relationship because previous literature pointed toward such relationship. Nonlinear relationships can also be modeled and we discuss those procedures to model nonlinearity. Furthermore, our discussion includes the use of regression diagnostics to identify outliers and to make decisions in the retention of data points versus the change in results once an outlier is removed. We also discuss how this information concerning outliers should be reported. We furthermore propose that researchers a priori hypothesize expected correlations between variables and we then discuss the benefits of performing a power analysis to determine needed sample size to detect that correlation with a reasonable probability. Power analysis can also be used to inform needed sample size to determine slope differences across groups. Lastly, the psychological sciences and other areas are going through a "replication crisis" and we discuss the need to replicate findings in the STEM fields. An example in biomaterials is provided to illustrate the pitfalls. In this example, the electrical resistance (R) is plotted with respect to the inverse temperature (T) of graphene and graphene adsorbed with nanomaterials. A total of six data points were collected for each system, fitted with a linear relationship, and the difference in slope between the two systems was offered as proof of a physically meaningful change of the system. Discussing this example will underscore the usefulness of the above approach and direct researchers into conducting statistically significant work that will elucidate processes that will withstand scrutiny and be reproducible.

23. Affordable Access to Cancer and Other Lifesaving Drugs in the United States

Dr. Evaristus Chiedu Obi

Abstract: The current trajectory of the astronomical increase in prices of cancer and other lifesaving drugs in U.S. is mind-boggling, and it has created enormous anxiety for most cancer patients and the society in general. Most cancer drugs typically cost more than $100,000 per year and recently a group of cancer researchers and physicians had vigorously questioned ethics of such exorbitant drugs priced out of reach for most buyers or patients. Cancer patients are forced to forgo or cut back on other vital needs and vital drugs etc. to pay for cancer drugs.

The free market approach currently emphasized and practiced in the United States has obviously failed to effectively address the out of control rising trend of the costs of cancer and other lifesaving drugs. Striking a delicate balance between promoting innovation and public interests is imperative in the current debate.

A broad-based approach to strategies for effectively dealing with the ethical issue of affordable access to cancer and other lifesaving drugs in U.S. was argued as a solution. These strategies would consist of reducing aggressive and costly advertising and marketing practices, implementing value-based reimbursement and pricing as well as Quality-Adjusted Life-Year (QALY) and Incremental Cost-Effectiveness Ratio (ICER), utilizing national evidence-based guidelines, flexible price controls and compulsory licensing for cancer and other lifesaving drugs especially in monopoly market environment. Some legislative proposals such as prescription drug importation from Canada, prohibition of anti-competitive pay-off agreements to keep more affordable generic equivalents off the market and to make sure consumers have access to the cost-saving generics they need are also argued as viable solutions. Providing for a Research and Development (R&D) allowance of about 20% like in British system for each pharmaceutical firm was argued as a solution to foster greater innovation.

24. The Establishment of Comprehensive Primary Health Care as a Critical Function of South-South Cooperation to Help Member Countries Combat Health Disasters

Dr. Evaristus Chiedu Obi; Dr. Peter I. Osuji

Abstract: Health disasters such as Ebola Virus disease, Lassa fever, Zika virus, and HIV/AIDs continue to emerge especially in the parts of the globe poorly prepared to handle them. These countries have inadequate or no primary health care (PHC) system. Guinea, Liberia, and Sierra Leone which were devastated by the recent Ebola Virus Disaster had inadequate health infrastructure, severe shortages of trained or qualified healthcare professionals (HCP), shortages of basic medicines, as well as very weak health information and disease surveillance systems. The contrast in the handling of the epidemic and the damages it caused in Nigeria vis-a-vis the other countries give us a deep insight into the essence of a good health care system, precisely, a PHC. PHC is the first line of action and plays an important role in the initial stage of an epidemic through initial response and surveillance.

Thus, we argue here that the best health system framework for preventing, containing and combating epidemics in developing countries is the comprehensive PHC. There is need to develop a good or adequate PHC (i. e., comprehensive PHC) system in each of the developing countries of the South. Left to some of the countries they cannot build a comprehensive PHC or an adequate PHC because of poor resources. We argue that a viable means of achieving this goal is through the South-South Cooperation (SSC). Therefore, besides the ongoing cooperation on health, one of the important and urgent functions of the SSC should be the establishment of the Comprehensive PHC in member countries.

The comprehensive PHC serves to address the underlying social determinants of health by employing intersectional action, and empowering communities, to meet the needs of the most marginalized as well as to offer comprehensive care. Furthermore, it emphasizes disease prevention and health promotion function that the governments of African Region find attractive and have recommitted themselves to. The community-oriented feature of the comprehensive PHC aligns with the communal value espoused by many of the member countries of the SSC.

25. Taking Care of our Caregivers: Ethics of Mental Health in Medical Students and Doctors

Polly Rinehart; Dr. Pamela Saha

Abstract: The high frequency of poor mental health of doctors and medical students has been well documented. Often it is labelled as burnout, and considered a normal part of the medical profession. Poor mental health has both personal and professional repercussions. Major contributors to poor mental health in medics and students include lack of support, workload, competition, sleep deprivation, suffering and dying of patients, pressure to cover costs of overhead when reimbursement is limited, and risk of liability when there might be a dispute about diagnosis. Furthermore, the normalization of burnout and depression among students and medics, and the stigmatization of mental health issues are some of many barriers to seeking help.

The brain arguably the most complicated organ in the body. When our other organs become diseased, we are generally good about seeking appropriate help, but often when our brains become ill, there is a pressure to hide it or "just deal with it". We view mental distress as a problem that a provider should be able to contain or overcome, while a somatic illness is considered beyond a provider's control. We even think that non-contagious illnesses should be endured stoically with minimal loss of work. This stigma against mental health issues robs people of their support network while dealing with mental illness. To decrease stigmatization and misconceptions about mental health, there must be an increase in both discourse and proactive support strategies. Self-awareness, self-care strategies, and faculty/administrative and peer led support systems are key to this. It is ethically wrong to ask doctors to take care of others at the expense of their own health. This presentation will explore reasons for mental health issues in medical professionals and students, testimonials from students, and suggestions for implementation of improved support strategies.

26. Ethical Engineering of Synthetic Biology Utilization & Effects

Darrell Robinson

Abstract: "Synthetic Biology will always have to establish a philosophy of evolving responsible practices and ethical standards due to synthetic biology manifesting from recombinant DNA tools with the ultimate application of evolved gene therapy. Two dangerous areas of synthetic biology that need to ethical transformation is Uncontrolled Release and Bioterrorism. Uncontrolled release of synthetic biology can be produced from synthetic biology being facilitated through open-source software and open-source catalogs of synthetic bio-parts. Bioterrorism of synthetic biology can be engineered from the methodical or accidental production of threatening microorganisms, especially without computational and biological risk assessment, regulation profiling, and function reversal or termination. One potential solution to decimate uncontrolled release and bioterrorism of synthetic biology is to create and maintain a classification level system of synthetic biology parts, products, and devices that show what these organisms can do individually, in tandem, and in specific conditioned bionetworks. This system must provide the essential criteria to qualify and verify of people and groups to use the databases and programs that create these new and modified life forms. This solution will establish a high standard of responsibility, discipline, and intent for synthetic biologists of every level. The second solution is to have every synthetic biology CAD program have a registered standard building object that can reverse the function and effect of a synthetic bio-product or terminate the bio-product completely (e.g., noise overload, reaction energy reduction, intron length variation, denaturation).). This solution will provide a safeguard function for negative synthetic biology effects, whether direct or indirect."

27. Understanding cases within professions

Invited Speaker Dr. Wade Robison

Abstract: It seems commonly assumed that presenting data is value-neutral. The data is what it is, and it is for those assessing it to make judgments of value. So a chart of earnings just tells us what a company has earned. The chart does not tell us whether the earnings are a good or bad sign. That valuation is to be made by those looking at the chart and is independent of the chart itself.

This view of the relation between presentations of data and value judgments is mistaken. Presentations are value-laden in at least two ways. How we choose to represent data is itself an ethically loaded value-judgment, and, second, presentations cause responses, including value-laden judgments.

We shall first look at how hard it can be to get inside a profession to be able to understand the problems those in that profession face so we can represent it properly. We shall then examine a case where a failure to understand the problem led to a mistaken moral judgment that has taken on a life of its own because of the power of how the problem is mistakenly presented.

28. Ethical Challenges for Human Subjects Research in Collaboration with Foreign Countries

Meghamala Sinha; Dr. Subrata Saha

Abstract: Human subjects' research that involve patients and volunteers from developed and developing countries involve many challenges, beyond the IRB approval and, conflicts of interest and other normal issues. The ethical standards for human research varies widely between countries. For instance, many hospitals in several developing countries like India do not have any IRB like committees. We have experienced that many clinicians there do not feel the need of IRB approval for questionnaire studies. Often the risks and benefits of various treatments are not fully explained to the patients. The selection criterion for clinical trials are also not strictly followed. However the clinical trials for drugs and medical devices are often carried out for lower costs and availability of a large number of patients. Human subjects' in these countries are unaware and also ignorant about their rights, welfare and the importance of informed consent. In this paper, we shall discuss these lack of ethical protocols and review boards in various developing countries in comparison to countries like USA, and possible steps to induce them for protecting human subjects from possible psychological and physical harm. We also discus on how this disparity in ethics practiced around the world causes difficulties for researchers to collaborate in internationally scalable projects.

29. Human death and a human determination of the moment of death - a study of the stormy debate over brain death and organ donation in Jewish law

Dr. Irit Offer Stark

Abstract: Death is not a pure biological concept. Although biological science can define the precise stage at which the organism is found, yet determining the exact moment of human death is influenced by subjective considerations, including moral, social, and theological considerations.

The determination of the moment of death evoked a heated debate in the Jewish law discourse. At the heart of this debate are different perceptions of "human death".

This phenomenon is not surprising, as it is consistent with the perception of the Jewish legal system as value system that influenced by an array of ethical considerations, as opposed to the concept of objective legal system with a tendency to formalism. And yet, this phenomenon is fascinating and constitute a highly notable example of the consequences

of such an essentialist - value legal system. In fact a critical question – whether a person is considered alive or dead – is determined according to the subjective ethical world view of the decisor.
In my lecture I would like to examine the different approaches of some of leading Jewish law authorities of the twentieth century regarding the determination of the moment of death, as well as to present the unique Israeli law on this issue.
While seeking to take into consideration the pluralism prevalent in Israeli society, the Israeli law raises moral dilemmas regarding distributive justice and the allocation of resources for medical treatment at the end of life.

30. Teaching ethics in an Advanced Education in General Residency Program (AEGD): preparing competent general dentists

Dr. Ram M. Vaderhobli; Dr. Linda Centore

Abstract: The Advanced Education General Dentistry (AEGD) Residency Program focuses on developing clinicians with sharp clinical reasoning, who behave in a patient-centered ethical manner, and demonstrate excellence in providing general dentistry. Most residency programs focus on technical clinical skills and emphasize "real world" training. Currently, there is no curriculum for residents that develop their ethical reasoning skills in preparation for the complex issues they will face during their yearlong training. Case-based everyday ethical dilemmas would help build their professional autonomy. The focus of this presentation is to discuss the need to include a curriculum module for residents on ethical reasoning, common ethical challenges, opportunity to discuss ethical dilemmas "on the fly", additional resources for consultation, and practice management implications.
Topics involving capacity for health care decisions, informed consent, adverse outcomes, loss of "good faith relationship", and firing a patient will be considered. We intend to identify an ethical framework that works for the postgraduate setting. We will also build a strong argument to support ethics training in AEGD Programs nationally. We will investigate funding opportunities and best practices for teaching methods, assessment, and calibration.

31. Bioterrorism, Biocrime and Biohacking: Anticipating the Ethical Issues

Dr. Richard L. Wilson; Dr. Michael W. Nestor

Abstract: The wide variety of microorganisms that can cause disease in humans is quite substantial – the estimate is that over 1,400 viruses, bacteria, and protozoa have been identified – but only a small amount of these carry the potential to appeal to bioterrorists. This paper focuses on three forms of biological threat--bioterrorism, biocrime and biohacking--the analysis will trace the history of biowarfare and terrorism. Organizations and groups drawn to biological aggression are discussed, along with the array of viruses, bacteria and toxins they might use in their attacks. The phenomenon of biocrime--biological aggression targeting individuals for personal rather than ideological reasons--is explored, along with the growing trend of biohacking.

We argue that the advance of biotechnology – in particular, the technology to synthesize ever larger DNA sequences – means that at least some of what bioweaponeers did with difficulty and with a large expense, can now be accomplished much more easily and inexpensively. Guerilla biohackers can accomplish and can duplicate with less time and less money, what previously required more resources. This is possible because Gene-sequencing equipment can be bought second-hand on eBay, and unregulated biological material can be purchased on the internet and then be delivered in a FedEx package, and can be misused.
In the past many security experts seem to have been committed to the idea that creating bioweapons – let alone recombinant pathogens – is extremely difficult, and "weaponizing" those agents is, for a number of reasons, nearly impossible. In addition many biologists, while not as optimistic about the difficulties, think that a preoccupation with bioweapons is counterproductive for two reasons. First, biodefense research tends to disseminate knowledge of how to develop such weapons; second, because we don't have a very good idea of how to defend ourselves against them.

The advance of biological knowledge has now offered malefactors, such as bioterrorists and biocriminals, with the possibility of developing and acquiring new categories of weapons with new opportunities for violence and the commission of biocrime. The biological revolution means determined actors can undoubtedly build a biological weapon.

Our analysis will present a historical overview followed by an anticipatory ethical analysis and will focus on bioterrorism, biocrime, and biohacking, will attempt to identify the dangers that are posed by new technological developments and the possibility of malevolent agents to subvert the life sciences in order to produce illness and death for malevolent ends.

32. Zika Eradication A Multidisciplinary and Anticipatory Ethical Analysis

Dr. Richard L. Wilson; Dr. Michael W. Nestor

Abstract: Microcephaly and other birth defects could be the tip of the iceberg," Dr. Sonja Rasmussen of the U.S. Centers for Disease Control and Prevention said at the annual meeting of the Pediatric Academic Societies. "The true burden of congenital disease with Zika virus is probably underestimated," said Dr. Marco Safadi of the Santa Casa Medical School in Sao Paulo, Brazil, who's been treating and studying cases.
Zika can be caused by misquitos and by sexual transmission.
The health care problems that occur due to Zika will be for children. As of May 2, 2016 Brazil has confirmed 2,844 cases of Zika in pregnant women. A direct causal link between Zika virus and microcephaly has been established. Newborns with microcephaly often act just like other newborns, perhaps a bit fussier. But the disabilities will appear as the growing children miss important milestones. They'll have learning deficiencies, vision problems and hearing problems, and many will also have physical disabilities. There is no cure.
Researchers have found that a paralyzing condition called Guillain-Barre syndrome can also occur but it is rare, effecting far fewer than 1 percent of patients: just 0.24 per 1,000. And Zika seems to cause a milder version of the condition, still putting patients into the hospital for 10 days or so.
Zika may stay around for years, citing a study just published that showed monkeys have been infected with Zika in Brazil. That means they can act as a reservoir for the virus, as they do with yellow fever.
Even if a vaccine is developed and people get vaccinated, or if enough of the population gets infected to confer widespread immunity, the monkeys will be there for the mosquitoes to bite and carry the infection back into people in the future.
This will make Zika a problem for years to come.
The question is how to control this disease vector.

In the design of GMM trials there are a number of ethical implications that need to be addressed. There is the issue of the nature and scope of host communities and how they will be affected. There is an obligation to respect host communities and to attempt to develop what protections need to be taken to ensure that host communities are respected.

Ethics involves the intentions, actions and the outcomes of actions as performed by actors. Anticipatory ethics is concerned with identifying potential problems with technology while it is in the early stages of development. In this paper we will extend the focus of anticipatory ethics to include the use of technology CRISPR genetic engineering technology to the project of genetically modifying mosquitos. The analysis will explore how CRISPR technology is now being used to modify mosquito populations in order to address human health

care problems and examine how the introduction of genetically modified mosquitos in Brazil has led to an end of the Zika health emergency.

33. Tele Surgery and Virtual Reality: Robotic Assisted Surgery Anticipating the Ethical Issues

Dr. Richard L. Wilson; Dr. Michael W. Nestor

Abstract: Robotic surgery, and robotically-assisted surgery refer to technological developments that use robotic systems to aid in surgical procedures. Robotically-assisted surgery was developed to overcome the limitations of pre-existing minimally-invasive surgical procedures and to enhance the capabilities of surgeons performing surgery.
In the case of robotically-assisted minimally-invasive surgery, instead of directly moving the instruments, the surgeon uses one of two methods to control the instruments; either a direct telemanipulator or through computer control. A telemanipulator is a remote manipulator that allows the surgeon to perform the normal movements associated with the surgery while robotic armshttps://en.wikipedia.org/wiki/Robotic_arm carry out those movements using end effectors and manipulators to perform the actual surgery on the patient. In computer-controlled systems the surgeon uses a computer to control the robotic arms and its end-effectors, though these systems can also still use telemanipulators for their input. One advantage of using the computerised method is that the surgeon does not have to be present, but can be anywhere in the world, leading to the possibility for remote medical treatment.
We are also beginning to see the emergence of medical applications for virtual reality (VR). These include telepresence surgery, three-dimensional (3-D) visualization of anatomy for medical education, VR surgical simulators, and virtual prototyping of surgical equipment and operating rooms. With VR and telepresence, a therapy can be effected electronically, regardless of the physical location of the patient. As these developments continue to occur applications will mediated through the computer interface, they present the embodiment of VR as the major force for change in the field of medicine. The Green Telepresence Surgery System is an example of how VR may change surgical training and practice. The next generation in medical education will be able to learn anatomy from a new perspective by "flying" inside and around the organs, using sophisticated computer systems and 3-D visualization. The VR surgical simulator is a stylized recreation of the human abdomen with several essential organs. Using this, students and surgeons can practice surgical procedures with virtual scalpels and clamps.
In the case of enhanced open surgery, autonomous instruments replace traditional steel tools, performing certain actions (such as rib spreading) with much smoother, feedback-controlled motions than could be achieved by a human hand. The main object of such smart instruments is to reduce or eliminate the tissue trauma traditionally associated with open surgery without requiring more than a few minutes' training on the part of surgeons. This approach seeks to improve open surgeries, particularly cardio-thoracic, that have so far not benefited from minimally-invasive techniques.

This paper will explore ethical and social issues with Tele Surgery and the increasing role of VR in such surgery focusing on the da vinci system. Our anticipatory ethical analysis will explore future developments with robotic surgery and the ethical and social issues that may arise. The analysis will explore issues with robotic surgery from the perspectives of the various stakeholder affected by the surgery.

34. Face Transplants: Ethical and Social Issues: An Anticipatory Ethical Analysis

Dr. Richard L. Wilson; Dr. Michael W. Nestor

Abstract: A face transplant is a medical procedure that is performed by replacing part or all of a person's face, using tissue after an injury, with the transplanted material coming from a donor cadaver. The world's first partial face transplant on a living human was carried out in France in 2005. The world's first full face transplant was completed in Spain in 2010. Turkey, France, the United States and Spain (in terms of the order of total number of successful face transplants performed) are considered the leading countries in the research into this procedure. This paper will explore the ethical and social problems related to face transplants and will explore issues that we can anticipate as arising as the technology continues to develop.
Our faces play an important role in our lives. Our face is a feature of our lived bodily experience which it is difficult to hide. We have facial expressions and we react to the facial expressions of others. Our faces play an important roles in social existence. There are many actions we perform with our faces, we breathe through our noses, we take in food through our mouths, and we see the world through our eyes.
To understand the ethical issues related to face transplants requires that we look at the issues related to facial transplants from different stakeholder perspectives. There are a variety of stakeholders who are affected by face transplants.
At the center of this group of stakeholders is the patient/recipient who are in need of a face transplant. These patients include burn victims, victims of accidents with severe facial disfigurement, as well as military personnel . For those with severe facial injuries there are both physical and psychological problems. Face transplants provide patients with the possibility of a return to 'normalcy' for those suffering from severe injuries.

In addition to the recipients there are surgeons, medical personnel and regulators, recipient families, donors and their families. Each of these people are affected by the processes of face transplant. Through a stakeholder analysis the ethical and social issues with face transplants will be explored.
What are the ethical and social issues with face transplants?
For Recipients
- Disfigurement can lead to a sense of a loss of identity
- A recipient wears someone else's face.
- There is a physical identity change which may have psychological effects.
- There is a need to use immunosuppressant drugs
What are the risks/benefits involved for recipients?
For Donor's
- There is need of a brain dead donor
- What issues arise for the donor's family?
Anticipated Social Problems
- What issues may arise for surgeons and medical personnel?
- Should the procedure be available for children?
- What issues may arise related to race and ethnicity?
- How will donor tissues be allocated?
For Recipients
- Unrealistic hopes
- There is the possibility of the rejection of the transplant
- There may be guilt related to the death of the donor
- There may be difficulties related to conforming to the treatment regiment and side effects
- Recipients may feel a personal responsibility fro the success of the procedure.
The aim of this analysis is to identify the ethical and social problems with face transplants and to perform an anticipatory ethical analysis on future cases involving face transplants.

35. Healthcare and Wearable Technology: Anticipatory Medical Ethics

Dr. Richard L. Wilson; Dr. Michael W. Nestor

Abstract: Wearable Technology (WT) has a variety of uses but is becoming increasingly important for self monitoring in health care and fitness. WT is also developing in conjunction with Big data analytics. Big data is being introduced in the insurance industry which brings about the potential need for increased regulations and restrictions regarding customer privacy. Important questions emerge such as should insurance companies have access to the personal information, including health information, that is tracked on the wearable technology devices? This paper will perform an anticipatory ethical analysis of WT.

Wearable Technology and Health

- Wearable technologies are becoming increasingly more popular
- Wearable technology can monitor live movements, heart rate, activity levels, and more
- Can calculate risk for individual and group health insurance plans with a far higher degree of accuracy.
- 2016: Around 275 million wearable electronic devices will be sold worldwide
- In 2017 they expected this number to rise to about 322 million which is about a 30 percent increase
- This increasingly popular technology can provide insight to insurance companies on how healthy individual's lifestyles are.
- 2/3 of insurance providers expect wearable technology to break into the insurance industry in a big way within the next year
- Around 30% of insurance providers already encourage their customers to buy these devices

Wearable Technology and Accidents

- Wearable technology isn't limited to things such as watches that record exercise habits
- Another category of wearables that can have an influence in insurance are wearable cameras.
- Camera's mounted on cars or other automobiles have the ability to record accidents
- Cameras can accurately record accident scenes, property damage and catastrophic events safely.
- These events can also be used as training tools for adjusters who are new to going to an accident to assess the damages.
- This will lead to more accurate accident reports and better training which has a much more positive future outlook for all parties involved as opposed to the wearables that track health.

Anticipated Obstacles to be Overcome

Before insurance companies can have access to the information contained on an individual's wearable technology, there are several obstacles that they must be addressed. The major concern is Privacy.

- This industry has yet to be regulated as the law is always slow to catch up to technology
- There is a gray line between what is right and what is wrong and until that is defined by law then there will be many ethical dilemmas.
- Can insurance companies use your data without permission?
- Can they discriminate against customers based on this information?
- What types of information will they try to obtain?
- Will they begin to require all of their customers to wear this type of technology?
- In that case what would happen if you can't afford or are not willing to use it? Will they cancel your insurance?

Recommendations

- As long as it is not required by insurance companies to have access to the data on wearable technology, users should sign a consent form which will allow them to decide for themselves what information the insurance companies can have access to the Data collect by WT.
- For insurance companies, they can offer incentives in the form of discounts to persuade healthy customer to share their data. For example car insurance companies put speed devices in cars.
- Universal Healthcare that prohibits insurance companies from overcharging healthy people, either from the high risk people dropping out or from predictive costs. Lawmakers could also prohibit the data and methods that insurance providers can use, which would be incredibly difficult.
- Government entities have a responsibility to keep Americans' medical records private. Adjusting HIPAA regulations could secure medical data within the walls of companies making the devices. Either companies need to partner with HIPAA partners or become HIPAA regulated.

36. Ethical Guidelines for Authorship

Dr. Pamela Saha; Dr. Subrata Saha

Abstract: The requirements of authorship are often presumed to be obvious. Yet, the placement and order of names on a publication often generate conflict among professionals. Prominent scientists peripherally involved may even be listed as first author in order to increase chances for acceptance for publication. The common cultural misuse of authorship for expedience or the exploitation of subordinates by heads of labs and by department chairs has led to problems beyond the inappropriate attribution of credit for work. Those listed as authors who had little involvement with a publication are ill prepared to take responsibility for the content presented to a Journal. When data can't be supported or verified by the authors listed, this presents a potential embarrassment for the attributed authors and editors of journals alike. As a result, journals are now establishing strict guidelines for authorship stating that an author must have contributed significantly to a publication. For example, a colleague who secured the financial support for a project, but did not participate in conducting the experiment, writing the paper or academic supervision of the project should not be included as an author. In this paper, we shall discuss the ethical problems associated with authorship in scientific publications.

37. The Bioethics OF Implantable Biohybrid Systems

Dr. Ranu Jung; Andres Pena

Abstract: There is growing interest in developing medical implants that merge with the biological systems in order to restore human function that is missing due to injury or disease. The integration of technology with biology (Biohybrid Systems) is pursued in an effort to make medical devices more effective. Modern understanding of biological systems has given scientists and engineers the tools to develop life-changing neuroprosthetic technologies such as cochlear implants, with well-established results in restoring hearing for thousands of people. Seamless integration of body and machine can potentially result in the embodiment of the implanted technology. For instance, implantable neural stimulators can help amputees embody their prosthesis by restoring sensation from their missing limb. Here we discuss the current state of development of some of these biohybrid systems and their future use; considerations of their safety, rigor in the testing metrics, and cyber security. We also discuss ethical issues that arise from such seamlessly integrated systems, such as the user's sense of self and cultural identity, functional restoration versus functional enhancement, and the effects of implant failure after embodiment.

**Please note abstract submissions are welcome after the official deadline. If accepted, abstracts will be displayed as a poster in the main conference area rather than as a podium talk.*

Poster Session

Bioethical Issues Associated with the Assessment of Growth of Mitral Valves Fabricated from Porcine Small-Intestinal Submucosa in a Nonhuman Primate Model
Brittany Gonzalez

Bioethics in Hydrodynamic Evaluation of Bioscaffold Mitral Valve in Child versus Adult Hemodynamic Settings
Elnaz Pour Issa

Bioethical Issues Concerning Gene Expression Analysis of Valvular Interstitial Cell Exposure to Media Derived from Oscillatory Flow Conditioned Valve Endothelial Cells
Sana Nasim

Understanding the Fundamental Tenets of Bioethics – Culture-sensitive Silos of Ethics vs. Multiculturalism/Pan- humanism/ Universalism
Dr. Amit Chattopadhyay

Ethical Perspectives in Use of state approved Medical Cannabis in Pediatric Epilepsy
Suicide Contagion in Teenagers: Ethical Issues in Depiction of Suicide in Media
Ethical Perspectives in Treatment of Symptomatic Infantile Spasms
Shefali Karkare

ADDITIONAL INFORMATION

Educational Objectives

At the conclusion of this workshop, participants will be aware of:

- Ethical guidelines for the development of new medical devices and new potential treatment modalities.
- Ethical issues involved in clinical trials and animal experiments.
- Conflicts of interest and regulatory issues for new devices.
- Research Integrity and Responsible Conduct of Research.

Target Audience

Engineers, Scientists, Physicians, Dentists, Lawyers, and graduate + undergraduate students.

Website

Online registration and latest program are available from
https://bioethicsconference.eng.fiu.edu

Special Needs

In accordance with the Americans with Disabilities Act (ADA), Florida International University seeks to make this conference accessible to all. If you have a disability that may require special accommodations, please contact Dr. Zachary Danziger at 305-348-0187 or zachary.danziger@fiu.edu

Hotel Information

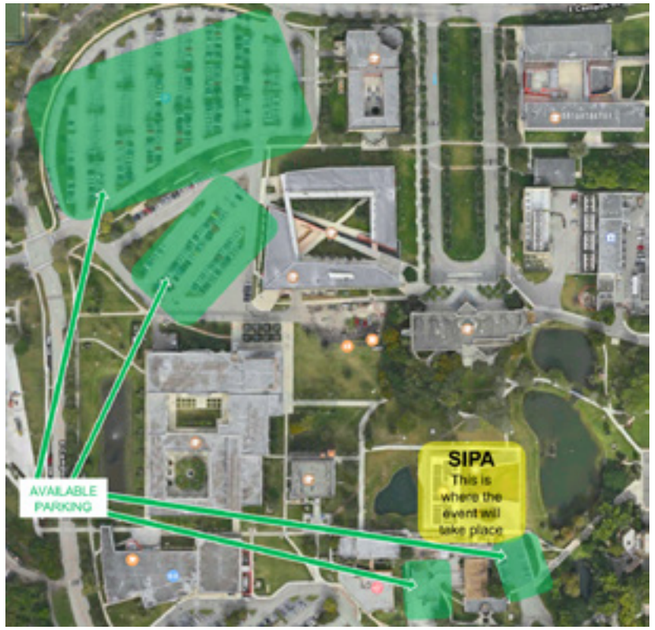
Intercontinental Hotel in Doral, FL is a fully renovated luxury hotel in Doral provides the comfort and innovative technology ideal for the discerning traveler. Their convenient location is seven miles from Miami International Airport an d minutes away from the conference location.
A block of rooms at the Intercontinental Hotel in Doral have been reserved at a special reduced rate of $129 (plus tax) per day for conference attendees during the conference. We advise you to call the hotel at 305-468-1400 and ask for their in-house reservations department. To receive the contracted rate, attendees should identify the group as ***9th International Conference on Ethics in Biology, Engineering, and Medicine***. The room block will be held until Tuesday, March 13th, 2018. After this date, rooms not reserved will be released.

Conference Location Information

Florida International University
11200 SW 8 St.
Miami, FL 33199

Steven J. Green School of Internation and Public Affairs
SIPA 125 Auditorium

Reception will be held in SIPA Atrium



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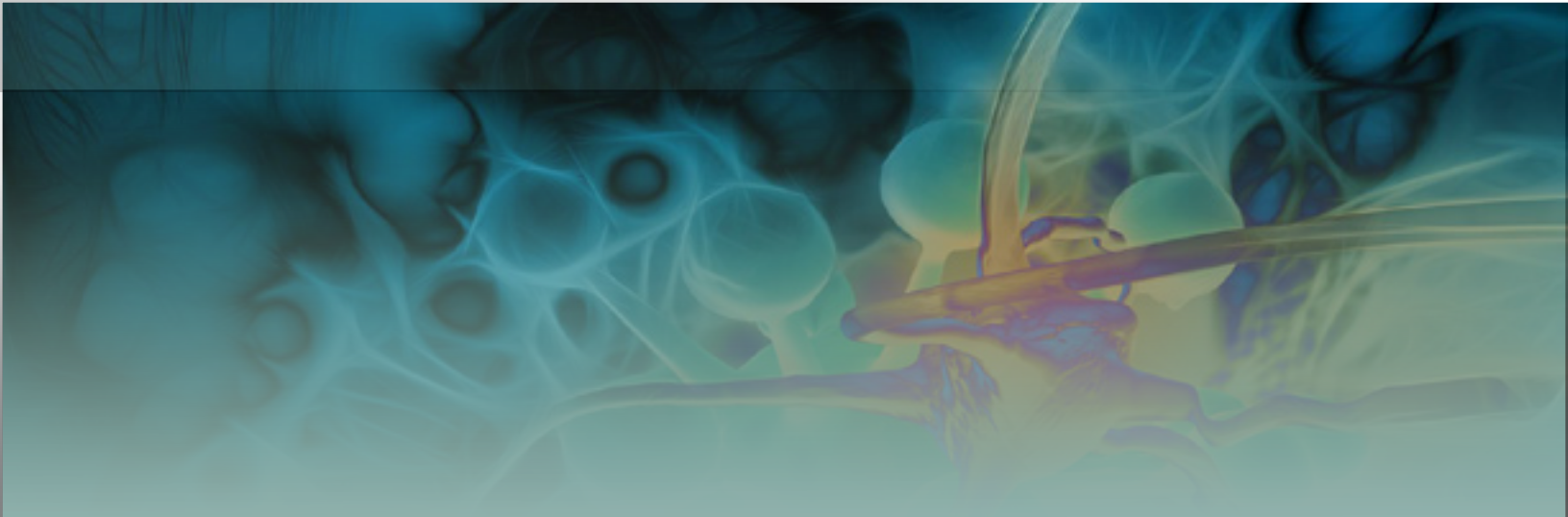

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